ID Code	FC 57

February 2011
(4th version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

JUNKOU Unseiin FC Extract Fine Granules for Ethical Use

(Unseiin)

Storage: Store at room temperature. See the section "PRECAUTIONS FOR HANDLING" Expiration date: The expiration date is indicated on the outer package.

Approval No.	(61AMY) 0418
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986

DESCRIPTION

(1) The daily dose of this product, 7.50 g, contains 5.10 g of the dried extract (Unseiin extract) from the following mixed crude drugs.
JP Japanese Angelica Root ---------- 4.00 g
JP Coptis Rhizome ---------- 1.50 g
JP Rehmannia Root ---------- 4.00 g
JP Scutellaria Root ---------- 3.00 g
JP Peony Root ---------- 4.00 g
JP Gardenia Fruit ---------- 2.00 g
JP Cnidium Rhizome ---------- 4.00 g
JP Phellodendron Bark ---------- 1.50 g
(JP: The Japanese Pharmacopeia)
The inactive ingredients contained are Corn Starch and Lactose Hydrate.

(2) This product is yellowish brown-colored fine granules, smells uniquely, and tastes bitter.
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INDICATIONS

The following symptoms of those patients with a sallow complexion and hot flushes:
Menstrual irregularity, dysmenorrhea, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, climacteric disturbance, and neurosis

DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5 g/day orally in 2 or 3 times before or between meals. The dosage may be adjusted according to the patient's age, body weight, and symptoms.

PRECAUTIONS

(1) Careful Administration (Unseiin should be administered with care in the following patients.)

1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, diarrhea, etc. may occur.]
2) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated]

(2) Important Precautions

1) When this product is used, the patient's "SHO" (constitution/symptoms) should be taken into account. The patient's progress should be carefully monitored, and if no improvement in symptoms/findings is observed, continuous treatment should be avoided.
2) When this product is coadministered with other Kampo-products (Japanese traditional herbal medicines), etc., attention should be paid to the duplication of the contained crude drugs.

(3) Adverse Reactions

This product has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

1) Clinically significant adverse reactions

① **Interstitial pneumonia**: If fever, cough, dyspnea, abnormal pulmonary sound, etc. are observed, administration of this product should be discontinued, and examinations such as chest X-ray or chest CT should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken.

② **Hepatic dysfunction and jaundice**: Hepatic dysfunction with elevation of AST(GOT), ALT(GPT), Al-P and γ - GTP level, and/ or jaundice may occur. The patient should be carefully monitored for abnormal findings. Administration should be discontinued and appropriate therapeutic measures should be taken, if abnormalities are observed.

2) Other adverse reactions

	Incidence Unknown
Hypersensitivity Note 1)	Rash, Redness, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Diarrhea, etc.

Note 1) If such symptoms are observed, administration should be discontinued.

(4) Use in the Elderly

Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.

(5) Use during Pregnancy, Delivery or Lactation

The safety of this product in pregnant women has not been established. Therefore, the product should be used in pregnant women, women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.

(6) Pediatric Use

The safety of this product in children has not been established. [Insufficient clinical data]

PRECAUTIONS FOR HANDLING

- Store at dry and cool place, protected from direct sunlight.
- Since this product contains natural crude drugs, some differences may be noted in the color or taste, etc. However, there is no change in the effect.

PACKAGING

210 g (2.5 g x 84 packets)

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Dep. of PMS Information,
Ohsugi Pharmaceutical Co., Ltd.
1-8-6, Yamasaka, Higashisumiyoshi-ku, Osaka 546-0035
050-3776-0358